
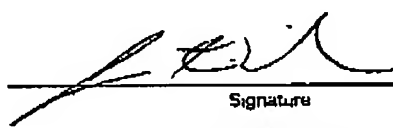


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 1001 1493101	
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		First Named Inventor ROBERT E. BURGMEIER	
		Art Unit 3763	Examiner CRIS LOIREN RODRIGUEZ
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. <input checked="" type="checkbox"/>			
This request is being filed with a notice of appeal. <input checked="" type="checkbox"/>			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. <input checked="" type="checkbox"/>			
I am the <input type="checkbox"/> applicant/inventor <input type="checkbox"/> assignee of record of the entire interest See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record Registration number <u>41,376</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number of acting under 37 CFR 1.34 _____		<u></u> Signature <u>J. SCOT WICKHEM</u> Typed or printed name <u>612.677.9050</u> Telephone number <u>JANUARY 23, 2006</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
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P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	ROBERT E. BURGMEIER et al.	Confirmation No.:	8195
Serial No.:	10/810,089	Examiner:	Cris Loiren Rodriguez
Filed:	MARCH 26, 2004	Group Art Unit:	3763
Title:	BALLOON CATHETER WITH RADIOPAQUE PORTION		
Docket No.:	1001.1493101	Customer No.:	28075

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I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office at 571-273-8300 on the date shown below	
<u>Thu H. Le-To</u> Type or print name of person signing certification	
 _____ Signature	<u>JANUARY 23, 2006</u> _____ Date

Dear Sir:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1-5, 7, 8, 12, 13, 15, 17, 18 and 20-23 stand rejected under 35 U.S.C. §102 over one or more of the following references: Hegde et al. (U.S. Patent No. 6,231,543), Voyles et al. (U.S. Patent No. 6,540,721), and Nishide et al. (U.S. Pub. No. 2004/0267280A1). However, in making these rejections, the Examiner failed to give due patentable weight to all of the language of the claims, contrary to relevant provisions of the MPEP and applicable case law. In particular, in paragraph 5 on page 3 of the Office Action of September 23, 2005, the Examiner stated as follows:

In response to arguments that the references do not have a radiopaque coating ...that is applied to the surface of the segment...in a fluid state and cured, this is not found persuasive because the claims are product-by-process claims and

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the steps of making has not been given patentable weight; only the product has been considered.

In this comment, the Examiner is referring to an element in each independent claim relating to a radiopaque coating, coating material, coating means, or a radiopaque portion that is applied in a fluid state and cured. An example of such language is found in claim 1: "the radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the shaft in a fluid state and cured." Such language cannot be merely dismissed as the examiner has done. There are two conceivable ways to read this language – as structural language or as product-by-process language. Applicants know of no third way permitted by the statutes or case law. In either way, this language imparts structural limitations to the claim as discussed below.

The best reading of the language of claim 1 is that it is defined in terms of structural language rather than in terms of product-by-process language. A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made. *Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989) citing *D. Chisum*, Patents §8.05, pp. 8-67 (1988). Therefore, in determining whether a claim is a product-by-process claim, the analysis becomes focused on particular claim limitations and on whether or not those limitations are process or structural in nature.

Process-sounding words such as "welded, intermixed, ground in place, press fitted, and etched" should be considered structural "when the process limitation imparts distinctive structural characteristics to the final product." *In re Garnero*, 412 F.2d 276 (C.C.P.A. 1969). Like the "process limitations" cited in *Garnero*, the limitations in the current claims impart a distinctive structural characteristic of the final product claimed. In other words, in the claims at issue, distinctive structural characteristics are imparted to the final product due to the radiopaque coating, coating material, coating means, and/or radiopaque portion being applied in a fluid state and cured. Following the holding of *Garnero*, the language in each of the independent claims should be considered structural in nature.

Numerous other cases as well other persuasive authority also point out that some limitations that appear to be process limitations are actually structural in nature. One commentator used a straightforward example to illustrate this point:

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For example, the word 'frozen,' though descriptive of the freezing process, definitely describes an objective characteristic observable by inspection of the product. The courts have held a variety of such words not to be process limitations; typical are: 'intermixed' as descriptive of a composition of matter, 'ground in place' as descriptive of the manner in which spark plug porcelain is fitted into its shell, and 'pressfitted' as descriptive of a sheet metal structure. Saxe & Levitt, "Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice," 42 J. Pat. Off. Soc'y 528, 536 (1960).

Similarly, in the Hazani case, the patentee wished to have the phrase "chemically engraved" considered a product-by-process limitation. *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473 (Fed. Cir. 1997). The Federal Circuit refused to do so and, instead, held that language in question was structural in nature because when "read in context, [the limitation] describes the product more by its structure than by the process used to obtain it." *Id.* at 1479. Similarly, in the *R2 Medical Systems* case, an Illinois District Court indicated that the word "affixed" means "to be attached physically" and that recitation of the word "affixed" does not refer to the process of affixing but rather the structural result. *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F.Supp. 1397, 1425-26 (N.D. Ill. 1996).

Applicants further note that the terms such as those of claim 1: "disposed," "applied" and "cured" are all past participles used in an adjectival and not a verbal sense. In other words, claim 1 is not attempting to claim the processes of disposing, applying or curing, but rather it is attempting to claim the structural result. Applicants would also note that in the Office Action of April 14, 2005, claim 24 was withdrawn by the examiner because it was a product-by-process claim. Such an objection was not raised with any of the other claims, indicating that at that time, those other claims were not interpreted as product-by-process claims.

What, then, is the structure implied by the claim language? The structure implied by the claim language includes at least the following. The inner surface of the radiopaque coating is in contact with the surface of the portion of the shaft on which it is disposed. This contact is immediate (e.g. not separated by adhesives, fluxes, gaps created by variations in manufacturing tolerances, or the like) and extends over the entirety of the surface of the portion of the elongate shaft on which it is disposed. Further, there is a bond between the

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surface of the shaft and the inner surface of the radiopaque coating along the entire area of contact.

In the alternative, even if the claims are considered product-by-process claims "the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art." See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) and MPEP 2113. Indeed, the structure implied by the process steps must be considered. As the Federal Circuit says in *Atlantic Thermoplastics*, "ignoring the claim limits of a product-by-process claim would clash directly with basic patent principles enunciated by the Supreme Court and this court." *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 846 (Fed. Cir. 1992). To be clear, applicants are not arguing, contrary to case law and accepted practice, that the *processes* are to be accorded patentable weight during examination. Applicants here are pointing out that the *structure* implied by those processes must be given patentable weight. Applicants can find no evidence that the structure implied by the claim language was given patentable weight in the office action.

In none of the Office Actions is there any evidence that the Examiner considered the full structure implied by the claim language. The only language in any of the office actions with any specificity is that cited above: "In response to arguments that the references do not have a radiopaque coating...this is not found persuasive because the claims are product-by-process claims and the step of making has not been given patentable weight; only the product has been considered." Applicants are concerned not that the step of making has not been given patentable weight, but rather that the structure implied by those steps has not been given patentable weight. The Examiner's assertion on the same page that "the claims do not have enough structural language to overcome the references" leads applicants to this conclusion (namely that the structure implied by the language has not been given patentable weight). For example, Hegde et al. (U.S. Patent 6,231,543) was cited as a piece of anticipatory art under 35 U.S.C. § 102. In Figure 4 a sleeve 50 may be disposed over a valve 40. However, if this sleeve is applied to the surface of the segment in a fluid state and cured (in a manner like that recited in claim 1), the valve would be rendered non-operative. Applicants cannot but help

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come to the conclusion, therefore, that the structure implied by the claim language has not been given due patentable weight.

Such language may be found in all independent claims. Claim 17 recites "the radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the portion of the inner tubular member in a fluid state and cured," claim 21 recites "where the non-metallic coating material is applied to the surface of the segment of the shaft in a fluid state and cured," claim 22 recites "wherein the coating means is applied in a fluid state and cured" and claim 23 recites "the radiopaque portion applied to the surface of the segment of the shaft in a fluid state and cured."

If such language were treated as structural language or as product-by-process language where the structure implied by the language was given due patentable weight, the differences between the claimed invention and the cited prior art would be apparent, as described in responses to previous office actions, which are incorporated herein by reference.

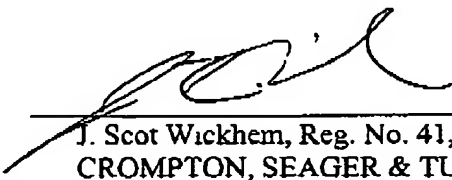
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

ROBERT E. BURGMEIER et al.

By their Attorney,

Date: January 23, 2006


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